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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,137	01/10/2006	Patrick Wuthrich	SERVIER 480 PCT	6126

25666 7590 10/13/2009  
THE FIRM OF HUESCHEN AND SAGE  
SEVENTH FLOOR, KALAMAZOO BUILDING  
107 WEST MICHIGAN AVENUE  
KALAMAZOO, MI 49007

EXAMINER
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SOROUSHI, LAYLA

ART UNIT	PAPER NUMBER
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1627

MAIL DATE	DELIVERY MODE
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10/13/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/564,137

**Applicant(s)**

WUTHRICH ET AL.

**Examiner**

LAYLA SOROUSH

**Art Unit**

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-27 is/are pending in the application.
- 4a) Of the above claim(s) 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CI/CC)  
Paper No(s)/Mail Date 8/1/06, 1/10/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The Office Action is in response to the Applicant's reply filed August 24, 2009 to the restriction requirement made on July 20, 2009.

Applicant's election of Group I claims 13-24 with traverse is acknowledged. The traversal is on the ground(s) that the inventions are closely related, and would most efficiently be examined in a single application is not persuasive

In response, Examiner respectfully reiterates in "a group of inventions claimed in an international application unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in PCT Rule 13.2 as meaning those features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description or drawings (if any)." The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. In the instant case the pharmaceutical composition is disclosed by the prior art so there is no novel product as claimed, and therefore, there is a lack in unity (US Pat 5,472,979). Applicant's arguments are not found persuasive.

The requirement is still deemed proper and is therefore made **FINAL**.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavielle et al. (US Pat 5,472,979) in view of Tanno et al. (US Pat 6171616).

Lavielle et al. teaches the compound of formula (I) its enantiomer or addition salt (see claim 1) in 10 g (14.06%), wheat starch and lactose in 110 g (85.9%), talc (lubricant) in a tablet formulation (see Example 24). Lavielle teaches salts such as sodium salt. The reference further teaches "in general, the unit dosage is graduated between 10 and 200 mg for a treatment taken 1 to 3 times per 24 hours."

Lavielle et al. fails to specifically teach the lactose and starch as a co-dried granule, the R configuration, and 5% to 10% by weight of compound A.

Tanno et al. teaches granulates of lactose and starch useful in tablet formulations having adequate hardness and at the same time disintegrates quickly for easy absorption. The tablets disintegrate in 1.7 minutes and have a hardness of 1.5 kgf (14.7 Newtons). The solid preparation can contain other additives such as sweetening agents.

The difference between the present claims and prior art is that applicants claim the R isomer whereas the prior art discloses the racemate (or any enantiomer). However, it is generally known in the art that normally, one of the enantiomers of a

racemate would possess a disproportionate amount of the desired biological activity. This would motivate one of ordinary skill to isolate the separate enantiomers in order to determine which of the two is most effective for the desired purpose. In addition, the isomer/enantiomer of a racemate is prima facie obvious. In *re Adamson*, 125 USPQ 233 (1960).

The determination of optimal or workable percentage by weight of compound A and disintegration rate by routine experimentation is obvious absent showing of criticality of the claimed percentage or rate. One having ordinary skill in the art would have been motivated to do this because Lavielle teaches "in general, the unit dosage is graduated between 10 and 200 mg for a treatment taken 1 to 3 times per 24 hours" and Tanno et al. teaches modifying granulate hardness changes disintegration rate. The percentage by weight of compound A and rate is deemed to be manipulatable parameters practiced by an artisan to obtain the best possible pharmaceutical results.

Claim 23 are product by process claims. It is well settled in patent law that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. See MPEP § 2123. The court in *In re Thorpe* held, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, the method of

making the composition as claimed does not render structural limitations to the claimed composition. Thus, the processes are not given patentable weight. In claim 23, the tablet "is obtained by direct compression" is not given patentable weight.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627